

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Dotan, *et al.* CONFIRMATION NO. : 7868
SERIAL NUMBER : 10/634,309 EXAMINER : Gerald R. Ewoldt
FILING DATE : August 4, 2003 ART UNIT : 1644
PATENT NO. : 7,537,900 ISSUE DATE : May 26, 2009
FOR : METHOD FOR DIAGNOSING MULTIPLE SCLEROSIS

VIA EFS

RESPONSE TO DECISION ON REQUEST FOR RECONSIDERATION OF PATENT
TERM ADJUSTMENT UNDER 37 C.F.R. §1.705(d)

Applicants submit this paper in response to the Decision on Request for Reconsideration of Patent Term Adjustment under 37 CFR 1.705(d) ("Decision") mailed on September 29, 2009. A response to this Decision must be filed by October 29, 2009. Applicants believe no fees are due with the filing of this Response. However, if any fees are required, Applicants hereby authorize the Commissioner to charge such fee, or credit any overpayment in fees, to Deposit Account No. **50-0311**; Customer Number **30623**; Reference Number: **25681-501**.

The Decision (copy enclosed) indicated that application for patent term adjustment filed on July 24, 2009 was granted-in-part and dismissed-in-part. Specifically, the Office agreed that delay due to the Amendment After Notice of Allowance under 37 CFR 1.312 filed on February 5, 2009 and the Response to Rule 312 Communication, mailed February 27, 2009, is **23 days**, not 111.

However, the Office submits that an additional Applicant delay should be noted in connection with the filing of the Communication on March 11, 2009. As the Office did not address the Communication, the period of adjustment ends on the date of the patent issued, May 26, 2009. Therefore, the Office noted an additional 77 days of Applicant delay. Applicants disagree.

Applicants submit this Communication was filed to record the results of the telephonic interview with the Examiner on March 4, 2009. A copy of the Communication is enclosed. Specifically, the Examiner objected to the previously filed formal drawings in the Response to

Rule 312 Communication mailed on February 27, 2009. During the telephonic interview, the Examiner indicated that new formal drawings were no longer required. In the telephonic interview, Applicants told the Examiner that they would submit a summary of the interview. Applicants therefore filed a Communication recording the details of the telephone call to establish in the record that no response to Rule 312 Communication was required. Therefore, Applicants submit that there should be no delay in connection with the Communication filed on March 11, 2009.

Further, Applicants' request for an additional 467 days of Office delay based on the fact that the above-referenced patent was pending for more than three years was dismissed. Applicants disagree.

Applicants maintain their assertion that there should be an additional 467 days of patent term adjustment due to the fact that the above-referenced patent was pending for more than three years in view of the U.S. District Court decision in Wyeth v. Dudas (D.D.C. 2008) on September 30, 2008. Again, according to the provisions of 37 C.F.R. §1.702(b), Applicants are entitled to Patent Term Adjustment for the failure of the Office to issue the patent within three years after the date on which the application was filed. Under 37 C.F.R. §1.702(b)(1)-(5), Applicants are entitled to this adjustment for any time other than any time consumed by continued examination of the application requested by the applicant under section 132(b), beginning on the date on which a Request for Continued Examination was filed, May 1, 2008, and ending on the date the patent issues.

The amount of the Adjustment under 37 C.F.R. §1.702(b) is calculated from August 5, 2006 (*i.e.*, the day after the date that is three years from the date that the application was filed), through and including April 30, 2008, the day before the date the Request for Continued Examination was filed, subtracting only time legitimately attributable to applicant delay. Applicants submit that the Adjustment under 37 C.F.R. §1.702(b) is 635 days. However, the delay under 37 C.F.R. §1.702(b) overlaps with delay under 37 C.F.R. 1.702(a) from May 18, 2007 through November 1, 2007, which is a total of 168 days of overlap. Thus, Applicants request that the term of the patent be extended for an additional $635 - 168 = 467$ days.

Applicants submit that the Patent Term Adjustment should be $(721 + 467 - 197) = 991$ days.

U.S.S.N.: 10/634,309

Applicant: Dotan, *et al.*

In addition to the foregoing, a Terminal Disclaimer was filed on October 15, 2008 directed to US Application No. 10/835,607. In accordance of the facts stated above, Applicants respectfully request review of the determination of patent term adjustment under 35 U.S.C. § 154(b).

If the Office would like to discuss any aspect of this filing, the Office representative assigned to process this request is welcome to call the undersigned attorneys.

Respectfully submitted,

IA Beattie

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Date: October 27, 2009

Enclosures:

Copy of Decision on Request for Reconsideration of Patent Term Adjustment
Copy of Communication filed March 11, 2009

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VIA EFS

Date of Deposit: March 11, 2009

Attorney Docket No.: 25681-501 UTIL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Dotan, *et al.*

SERIAL NUMBER: 10/634,309

EXAMINER: Ewoldt, Gerald R.

FILING DATE: August 4, 2003

ART UNIT: 1644

FOR: METHOD FOR DIAGNOSING MULTIPLE SCLEROSIS

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COPY

COMMUNICATION

This paper is in response to the Response to Rule 312 Communication dated February 27, 2009 in the above-identified application. On February 5, 2009, Applicants paid the Issue Fee and filed an Amendment after Notice of Allowance under 37 C.F.R. § 1.312 in order to submit formal replacement drawings in the above-identified application. In his Response to Rule 312 Communication, the Examiner indicated that the Amendment was disapproved due to objections to the submitted formal drawings. *See*, Response to Rule 312 Communication at page 1.

Applicants thank the Examiner for the courtesy extended during the telephonic interview of March 4, 2009, in which the Examiner indicated that formal drawings are no longer required. Applicants respectfully request early passage to issue of the present application.

No fees are believed due. The Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 25681-501 UTIL.

Respectfully submitted,

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Dated: March 11, 2009



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OFFICE OF PETITIONS

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In re Patent No. 7,537,900 :
Dotan, et al. : DECISION ON
Application No. 10/634,309 : REQUEST FOR
Issue Date: May 26, 2009 : RECONSIDERATION OF
Filed: August 4, 2003 : PATENT TERM ADJUSTMENT
Attorney Docket No. : AND NOTICE OF INTENT TO
25681-501 : ISSUE CERTIFICATE OF
: CORRECTION

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d), filed July 24, 2009. Patentees request that the determination of patent term adjustment be corrected from four hundred thirty-six (436) days to nine-hundred ninety-one (991) days.

The request for reconsideration of the patent term adjustment indicated in the patent is GRANTED to the extent indicated herein.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond. No extensions of time will be granted under 37 CFR 1.136.

The patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of four hundred forty-seven (447) days.

BACKGROUND

This application was filed on August 4, 2003. On May 26, 2009, the application matured into U.S. Patent No. 7,537,900 with a revised patent term adjustment of 436 days. The Office determined that the 636 days of Office delay pursuant to 35

U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b)^{1,2} overlaps with the 721 days of Office delay pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1) and (a)(2)^{3,4} accorded prior to the issuance of the patent. As such, the Office allowed only entry of the adjustment of 721 days for Office delay. No additional days of patent term adjustment were entered at issuance under the three-year pendency provision. The patent issued with a revised patent term adjustment of 436 days (721 days of Office delay - 285 days of applicant delay.)

¹ Pursuant to 35 U.S.C. 154(b)(1)(B), 37 CFR 1.702(b) provides, in pertinent part, that:

Failure to issue a patent within three years of the actual filing date of the application. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including:

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b) [.]

² As of the filing of the RCE on May 1, 2008, the application was pending three years and 636 days.

³ 37 CFR § 1.702, provides grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

(a) Failure to take certain actions within specified time frames. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to:

(1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international application;

(2) Respond to reply under 35 U.S.C. 132 or to an appeal taken under 35 U.S.C. 134 not later than four months after the date on which the reply was filed or appeal was taken;

⁴ A first Office action was not mailed until April 10, 2006, fourteen months and 553 days after the application filing date of August 4, 2003. A final rejection was mailed November 1, 2007, four months and 168 days after a reply was filed on January 17, 2007.

On July 24, 2009, patentees timely submitted this request for reconsideration of patent term adjustment asserting that the correct number of days of Patent Term Adjustment is 991 days, based in part, under the courts interpretation of the overlap provision as set forth in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees asserts that pursuant to Wyeth, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentee maintains that the total non-overlapping PTO delay under § 154(b)(1)(A) & (B) is 1,188 (721 + 467) days as these periods do not occur on the same day.

Patentees further asserts that the period reduction of 111 days under 37 CFR 1.704(c)(10) for filing an amendment under § 1.312 and drawings on February 5, 2009, after the mailing of the notice of allowance, is incorrect. Rather, the period adjustment set forth in § 1.703 should be reduced by only 23 days.

OPINION

Patentees dispute the reduction of 111 days for filing the amendment under § 1.312 and drawings on February 5, 2009, after the mailing of the notice of allowance pursuant to 37 CFR 1.704(c)(10). Specifically, patentees assert that the Office mailed a "Response to Rule 312 Communication" in response to the amendment and drawings on February 27, 2009. Patentees contend that the period of reduction should be 23 days (not 111 days), counting the number of days beginning on the filing date of the amendment under § 1.312 and drawings, February 5, 2009, and ending of the mailing date of the "Response to Rule 312 Communication", February 27, 2009, in response to the amendment under § 1.312 and drawings.

Patentees' contention is well taken. 37 CFR 1.704(c)(10) provides that:

Submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

- (i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice

in response to the amendment under § 1.312 or such other paper;

or

(ii) Four months;

In this instance, the record reveals that the Office took action in response to the filing of amendment under § 1.312 and drawings on February 27, 2008. Accordingly, the period of adjustment of the term of the patent should have been reduced by 23 days, not 111 days. The period of reduction of 111 days will be removed and a period of reduction of 23 days will be entered.

However, a further review of the application history reveals that patentees should have been assessed an additional period of delay for the filing of a "COMMUNICATION" on March 11, 2009, after the mailing of the notice of allowance, which under the circumstances of this application, is a ground for reduction of patent term adjustment under 37 CFR 1.704(c)(10).

In this instance, it is undisputed that patentee filed the "COMMUNICATION" after the mailing of the notice of allowance. The Office did not address the "COMMUNICATION" before the issuance of the patent. Thus, the period of adjustment should have been reduced by the lesser period of 77 days, beginning on the date the "COMMUNICATION" was filed, March 11, 2009, and ending on the date the patent issued, May 26, 2009. Accordingly, a period of reduction of 77 days will be entered.

With regard to the argument under 37 CFR 1.702(b), patentees' interpretation of the period of overlap has been considered, but found inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A).

Patentees' interpretation of the period of overlap has been considered, but found inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A). 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the

patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f)⁵ and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

Further, as stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of*

⁵ Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office beginning on the application filing date under 35 U.S.C. 111(a), August 4, 2003, and ending on the date of filing of a request for continued examination (RCE), May 1, 2008, (not including any other periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)). The relevant period ends with the filing of the RCE as the three-year time frame specified in 35 U.S.C. 154(b)(1)(B) does not include the period subsequent to the filing of the RCE. 35 U.S.C. 154(b)(1)(B)(i).

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1) and (a)(2), 721 days of patent term adjustment were accorded during the pendency of the application for Office delay prior to the filing of the request for continued examination. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), 636 days of patent term adjustment accrued for Office issuance of the patent more than 3 years after the filing date of the application⁶.

⁶The Office notes that patentees incorrectly calculated the period of adjustment under 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b) ("Three Years Delay"). Furthermore, patentees used the incorrect Three Years Delay period in calculating the requested patent term determination. Pursuant to 37 CFR 1.703(b), the period of adjustment is 636 days (not 635 days as suggested by patentees), counting the number of days in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a), August 5, 2006, and ending on the date the request for continued examination was filed, May 1, 2008. "When a period is

All of the 636 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 721 days of patent term adjustment under 37 CFR 1.702(a)(1) and (a)(2). Entry of both the 721 days and the 636 days is neither permitted nor warranted. 721 days is the actual number of days issuance of the patent was delayed.

CONCLUSION

In view of, the patent term adjustment indicated on the patent should be 447 days (721 days of Office delay - 274 (84 + 90 + 23 + 77) days of applicant delay)).

This matter is being referred to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by 447 days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Kenya A. McLaughlin, Petitions Attorney, at (571) 272-3222.

Christina Tartera Donnell
Christina Tartera Donnell
Senior Petitions Attorney
Office of Petitions

Enclosure: Copy of DRAFT Certificate of Correction

indicated (in 37 CFR 1.703 or 1.704) as 'beginning' on a particular day, that day is included in the period, in that such day is 'day one' of the period and not 'day zero.'" MPEP 2731. "For example, a period beginning on April 1 and ending on April 10 is ten (and not nine) days in length." Id.